Summary Information

510(k) Summary

SEP 2 4 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072443

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041

Contact Person: Marlene A. Hanna

2. **Preparation date**

Date Special 510(k) prepared: August 29, 2007

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products Ca DT Slides
Common Name: calcium test
Classification Name: Calcium test system (21 CFR 862.1145)

VITROS Chemistry Products DT Calibrator Kit
Common Name: calibrator
Classification Name: Calibrator (21 CFR 862.1150)

4. **Predicate device**

The VITROS Chemistry Products Ca DT Slides (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to the VITROS Chemistry Products Ca DT Slides (current slide) and VITROS Chemistry Products DT Calibrator Kit. The FDA cleared the VITROS Chemistry Products Ca DT Slides on May 12, 1987 (K870035) under the product name KODAK EKTACHEM DT SLIDES (Ca). With the purchase of KODAK Clinical Products Division by Johnson and Johnson in 1994, the product branding was revised to VITROS Chemistry Products Ca DT Slides The most recent FDA clearance for the VITROS Chemistry Products DT Calibrator Kit was May 25, 2007 (K071216).

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5. Device Description

The VITROS Chemistry Products Ca DT Slide assay is performed using the VITROS Chemistry Products Ca DT Slide and the VITROS Chemistry Products DT Calibrator Kit on the VITROS DT60/ DT60 II Chemistry Systems. The VITROS Ca DT Slide is a multilayered, analytical element coated on a polyester support. All reactions necessary for a single quantitative measurement of calcium take place within the multi-layered analytical element of a VITROS Chemistry Products Ca DT slide.

A drop of patient sample is deposited on the VITROS Ca DT Slide and is evenly distributed by the spreading layer to the underlying layers. The bound calcium is dissociated from binding proteins, allowing the calcium to penetrate through the spreading layer into the underlying reagent layer. In the reagent layer, the calcium forms a complex with Arsenazo III dye, causing a shift in the absorption maximum.

After incubation, the reflection density of the colored complex is measured spectrophotometrically. The amount of colored complex formed is proportional to the calcium concentration in the sample fluid. The test result is reported in milligrams per deciliter (mg/dL) or millimoles per liter (mmol/ L).

VITROS Chemistry Products DT Calibrator Kit contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from bovine serum albumin and processed bovine serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added. The companion diluents are prepared from processed water to which inorganic salts have been added.

The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS Chemistry Products Ca DT Slides
For *in vitro* diagnostic use only. VITROS Ca DT Slides quantitatively measure calcium (Ca) concentration in serum and plasma.

VITROS Chemistry Products DT Calibrator Kit
For *in vitro* diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMY, AST, TBIL, NBIL, BUN/CREA, Ca, CHOL, CK, Cl^-, CO_2, CREA, CRSC, Fe, GGT, GLU, HDLC, K^+, LAC, LDH, LIPA, Mg, Na^+, NH_3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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7. Comparison to predicate device

The VITROS Chemistry Products Ca DT Slide (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to VITROS Chemistry Products Ca DT Slide and VITROS Chemistry Products DT Calibrator Kit, which were Cleared by the FDA for *in vitro* diagnostic use.

VITROS Chemistry Products Ca DT Slide: (K870035, cleared May 12, 1987)
VITROS Chemistry Products DT Calibrator Kit: (K071216, cleared May 25, 2007).

Table 1 lists the characteristics of the tests performed using the VITROS Ca DT Slide (modified) and the VITROS Ca DT Slide (current).

Table 1. List of VITROS Chemistry Products Ca DT Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS Chemistry Products Ca DT Slide (Modified)	Predicate Device VITROS Chemistry Products Ca DT Slide (Current)
Intended Use	No Change.	For *in vitro* diagnostic use only. VITROS Ca DT Slides quantitatively measure calcium (Ca) concentration in serum and plasma.
Fundamental scientific technology	No Change.	Dry, multilayered slide utilizing spectrophotometrics
Test Type	No Change.	Colorimetric
Reactive Ingredients per cm^2	No Change.	Arsenazo III dye 60 µg
Sample type	No Change.	Serum and plasma
Instrumentation	No Change.	VITROS DTSC/ DTSC II Analyzers
Composition of the Spreading Layer* component of the VITROS Ca Slide	TiO2: New Supplier Cellulose Acetate: New lot Estane: Increased to 1.7 times the current level, i.e. 70% increase. Estane concentration is correlated to manufacturability of the VITROS Ca Slide. Surfactants: No Change.	TiO2, Cellulose Acetate, Estane, Surfactants.
Manufacturing Process Changes due to the increased Estane level in the Spreading* Layer Component of the VITROS Ca Slide	The increased concentration of Estane raised the viscosity, requiring modifications to the solution delivery system and to the non-solvent flow rate.	Current Manufacturing Process.

*The "Spreading Layer" refers to the spreading layer component of the VITROS Chemistry Products Ca DT Slide (Refer to Page 2 of the Instructions For Use for VITROS Chemistry Products Ca DT Slides). The Spreading Layer evenly distributes sample fluid to the underlying layers of the VITROS Ca DT Slide.

No modifications were made to VITROS Chemistry Products DT Calibrator Kit.

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8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the VITROS Chemistry Products Ca DT Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured calcium values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products Ca DT Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
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Rochester, New York 14626-5101

SEP 2 4 2007

Re: k072443
Trade/Device Name: VITROS Chemistry Products Ca DT Slides
VITROS Chemistry Products DT Calibrator Kit
Regulation Number: 21 CFR§ 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY, JIX
Dated: August 29, 2007
Received: August 30, 2007

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072443

Device Name: VITROS Chemistry Products Ca DT Slides

Indication For Use: For *in vitro* diagnostic use only. VITROS Ca DT Slides quantitatively measure calcium (Ca) concentration in serum and plasma. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone disorders, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072443

Indication for Use

510(k) Number (if known): K072443

Device Name: VITROS Chemistry Products DT Calibrator Kit

Indication For Use: For *in vitro* diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for ALB, ALKP, ALT, AMY, AST, TBIL, NBIL, BUN/CREA, Ca, CHOL, CK, Cl^-, CO_2, CREA, CRSC, Fe, GGT, GLU, HDLC, K^+, LAC, LDH, LIPA, Mg, Na^+, NH_3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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